

**HASQARD Focus Group**  
Meeting Minutes  
May 15, 2012

The meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:05 PM on May 15, 2012 in Conference Room 308 at 2420 Stevens.

Those attending were: Huei Meznarich (Focus Group Chair), Cliff Watkins (Focus Group Secretary), Lynn Albin, Taffy Almeida, Michael Barnes, Glen Clark, Scot Fitzgerald, Shannan Johnson, Larry Markel, Steve Smith, Noe'l Smith-Jackson, Chris Sutton, Cindy Taylor, Amanda Tuttle, Rich Weiss and Eric Wyse.

- I. Huei Meznarich requested comments on the minutes from the April 17, 2012 meeting. No HASQARD Focus Group members present stated any comments on the April meeting minutes and, after hearing no objections, the minutes were approved.
  
- II. The status of action items identified at the April 17 meeting was discussed.
  - a. A few hours before the meeting, Rich Weiss sent e-mail to the Focus Group to propose revised language for the last paragraph in Section 5.3 containing the sentence about measured radioactivity being reported along with its total propagated uncertainty but without comparison to the estimates *a priori* MDC. The Chair asked the group to review this e-mail, provide Rich comments as necessary and be prepared to approve the revision at the next Focus Group meeting in June.
  - b. Huei Meznarich reported that she looked up the definition of high purity water currently used in Section 6.1.1 and found it is equivalent to ASTM Type II water. Rich Weiss agreed to look into this matter and determine if a more appropriate definition can be specified in HASQARD.
  - c. Huei Meznarich reported that she has not yet had a chance to check MARLAP for acceptance criteria for analyte concentrations measured in method blanks and provide an alternative set of criteria for this QC element in Table 6-1. The due date for the action item was revised to June 12, 2012.
  - d. A few hours before the meeting, Rich Weiss sent e-mail to the Focus Group to propose revised language for the definition of the terms “Tracer” and “Carrier” for Sections 6.2.6 and 6.2.7 respectively. The Focus Group also discussed whether a volume-specific glossary should be added to each Volume. The Chair asked the group to review the e-mail, provide Rich comments as necessary and be prepared to approve the revision at the next

Focus Group meeting in June.

During this discussion, Chris Sutton mentioned he thought volume-specific glossaries would be good to help each volume be more “stand-alone.” He said he knew of samplers who only worry about meeting the requirements of Volume 2 instead of also meeting Volumes 1 requirements as part of their work. Other Focus Group members expressed concern about this as the intent of the HASQARD is to use Volume 1 with each of the other volumes because Volume 1 contains the quality assurance requirements applicable to all four volumes.

- e. Prior to the Focus Group meeting on May 15, 2012, a sub-committee met on the detection limit language found in Section 7.5 of HASQARD. Huei Meznarich will use the input received at that meeting to propose new language for inclusion in this section. That language will be distributed in an e-mail, and comments will be resolved at the next Focus Group meeting in June. The action item to convene a sub-committee on the topic of detection limits is closed.
- f. At the April 17 Focus Group meeting, the Focus Group Secretary was given the action item to redistribute the write-up on detection limits provided several months ago in an e-mail by Eric Wyse. That action item was completed on May 1, 2012 and supported the May 15 meeting of the sub-committee discussed above. The action item is closed.
- g. At the April 17 Focus Group meeting, Kris Kuhl-Klinger agreed to refresh her memory and remind the Focus Group what the reference to Section 4.1.5.1 DOE-1 in the QSAS says that provides relevance to the comment made on Section 7.7 of HASQARD. Kris provided a write-up that was subsequently provided to the Focus Group. After review of the material Kris provided, the Focus Group decided to strike the proposed revision from the document. The action item is closed.

III. The status of the preparations of Revision 4 for Volumes 1, 2 and 3 was discussed.

- a. The status of the review for Volume 2 was discussed. Chris Sutton reported that he has accepted and incorporated most comments received. He has begun addressing some of the WCH comments and will provide responses to these to the Focus Group Secretary soon. Chris believes that they will likely need to convene a sub-group meeting to discuss some of the issues associated with the comments. Chris acknowledged that we will need technical editing for all of the HASQARD Volumes when the revisions are accepted, but cautioned against the technical editors changing what is now very precise language. Technical editors often try

to “improve” the writing as they do their work but this can completely alter the meaning or deter the reader’s ability to comprehend the author’s intent.

- b. The status of the review for Volume 1 was discussed. Steve Smith reported that the version of Volume 1 that had been distributed by the Focus group Secretary prior to the meeting was the results of the gap analysis done to include the desirable QSAS material. The document has been revised by moving entire sections from one location to another. This gives the “tracked changes” version of the file the look of having whole sections revised where no change was made other than the location of the text. Therefore, the Focus Group will need to review Sections 4, 5, 6 and 10 to ensure the placement of the sections makes sense.

#### IV. HASQARD Volume 4, Revision 4 Proposals

At the conclusion of the April 17 Focus Group meeting, all proposed revisions to Volume 4 had been discussed by the Focus Group. The Focus Group Secretary was given the action to send out two files. One file showing the document with all proposed revisions highlighted by the “tracked changes” feature of the software and the second file showing the way the document would read if all changes were to be accepted. As the Focus Group Secretary was preparing to complete this action, the fact that several “unresolved issues” or “place holders” in the form of “Comment” boxes in the document still existed. Therefore, distribution of Volume 4 for a “draft final” review would be premature. The Focus Group began reviewing these outstanding comments.

A comment in Section 2.2 made by Kris Kuhl-Klinger was in the electronic version of the document that all comments were eventually incorporated into concerning the fact that daily monitoring of cold storage units on a calendar day (rather than work day) basis would be problematic for the 222S Laboratory on weekends. The Focus Group agreed that while it may be problematic, it does represent a practice that laboratories should be able to accommodate. The comment box was deleted and the text was unchanged.

A comment box was left in Section 3.3 regarding information that the laboratory sample receiving personnel need to review on the chain-of-custody form received with samples. The Focus Group made a comment that the material listed here needs to be checked with the content of Volume 2 to ensure that requirements for chain-of-custody records contain all of the information in this section at a minimum. Chris Sutton requested that the Focus Group Secretary forward the material listed in Section 3.3 to him and he will take the **ACTION ITEM** to review Volume 2 against this list.

A comment box was left in Section 4.0 to determine if the statement, “Equipment not calibrated by the user (e.g., an analytical balance) that is out of calibration must be clearly identified to prevent use” was covered anywhere else in the document. While not specifically covered, the Focus Group felt that control of use of out of calibration equipment was adequately covered by other statements in this Section and in Volume 1, Section 9. The sentence in questions was deleted.

A comment box in Section 4.3 asked about the origin of the proposed new sentence: “A program for verifying and documenting the accuracy of all standards shall be routinely followed.” This sentence was found to be something stated in the QSAS used by DOECAP. The Focus Group felt that striking that sentence was acceptable since the next sentence seemed to say the same thing. The following sentence, which remains in the proposed revision says, “A program and the criteria used to verify or re-verify standards, reagents, reference materials or other media potentially impacting the quality of reported results shall be defined and documented to assure that acceptable accuracy is maintained.”

A comment was left in Table 4-5 asking what was meant by “dedicated instrument” for cyanide analysis. The Focus Group members present agreed this was an acceptable statement. The comment was deleted and the text was left as revised.

A comment made on Section 5.1, “Data Review” stated the entire section needed to be revised and reconciled against Volume 1. The Focus Group agreed to take no action on this outstanding commitment until the review of Volume 1 was completed. This comment remains an outstanding issue requiring resolution prior to completion of the proposed revision to Volume 4.

The next comment box remaining in the document was in Section 5.3 and was related to Rich Weiss’s action item detailed in Section II.a of these minutes. This comment remains an outstanding issue requiring resolution prior to completion of the proposed revision to Volume 4.

The next comment box remaining in the document was in Section 6.1.1 and was related to Huei Meznarich’s action item detailed in Section II.b of these minutes. This comment remains an outstanding issue requiring resolution prior to completion of the proposed revision to Volume 4.

The next comment box remaining in the document was in Table 6-1 and was related to Huei Meznarich’s action item detailed in Section II.c of these minutes. This comment remains an outstanding issue requiring resolution prior to completion of the proposed revision to Volume 4.

The next comment box remaining in the document was a reminder to assess the use of the terms MDA vs. MDC in Table 6-1. The Focus Group agreed that MDC was a better term and all reference to MDA should be deleted from the table.

The next comment box remaining in the document was a reminder to check the accuracy of a parenthetical statement and acceptable relative percent difference (RPD) criteria associated with ICP/MS analysis of duplicates in Table 6-2. While not completely closing the matter by determining the values stated were acceptable and accurate, the Focus Group agreed to revise the language found in this criteria list for clarification. This comment remains an outstanding issue requiring resolution prior to completion of the proposed revision to Volume 4.

The next comment box remaining in the document was a reminder to check the accuracy of the acceptable internal standard recovery criteria associated with ICP/MS analyses Table 6-3. Eric Wyse had researched this matter and reported the criteria stated in EPA Method 6020. The Focus Group agreed to a criteria of  $\geq 30\%$  to  $\leq 120\%$ .

The next comment box remaining in the document was in Section 7.7 and was related to Kris Kuhl-Klinger's action item detailed in Section II.g of these minutes. The comment was resolved as stated in Section II.g of these minutes.

Another comment in Section 7.7 was to check the accuracy of the statement, "Additional information on the application, development, and use of control charts can be found in Washington State Department of Ecology (Ecology) 02-03-055, Procedural Manual for the Environmental Laboratory Accreditation Program." Huei Meznarich accepted the **ACTION ITEM** to check this reference. This comment remains an outstanding issue requiring resolution prior to completion of the proposed revision to Volume 4.

#### V. Discussion of Proposed Revisions to HASQARD Volume 1

After addressing all comments remaining as open items in Volume 4, the Focus Group began reviewing the electronic file containing revisions to Volume 1 of HASQARD that showed the results of the QA sub-group's gap analysis between QSAS requirements and HASQARD.

A sentence to provide clarity to the beginning of Section 5.1, "Initiation of Corrective Action" was accepted by the Focus Group. That sentence says, "Conditions adverse to quality, including failures, malfunctions, deficiencies, defective items, out-of-control processes, and nonconformances shall be identified."

A revision to a bullet in Section 5.1 that listed an example of a condition where investigation and corrective action determinations may be conducted was proposed as a change from “Diverse trends in the analysis of standards” to “Adverse trends in the analysis of standards.” This proposed revision was accepted.

The QA sub-group proposed the title of Section 5.3 be changed from “Root Cause Analysis” to “Causal Analysis” to provide clarification because a full root cause analysis process is not being discussed in this section. This proposed revision was accepted.

In Section 5.5, “Trend Analysis” the QA sub-group proposed an additional bullet in the list of quality-related information that can be analyzed when conducting trend analyses. The additional item is “lessons learned.” This item is listed in the QSAS Section 4.10 gray box DOE-1 but not in HASQARD. This proposed revision was accepted.

In reviewing Section 5.7, “Nonconformances” the Focus Group felt the word “samples” was not appropriate in the sentence, “Controls shall be implemented for samples/materials, parts, or components that do not conform to requirements to prevent their inadvertent use.” The word was struck from the sentence.

The Focus Group discussed a proposed revision to Section 6.0, “Documents and Quality Records.” The QSAS includes a reference to Operator Aids in Section 4.3 gray box DOE-1, and the proposed revision would add the term “operator aids” to Section 6.0. The sentence where operator aids was suggested for inclusion in the list would have read, “Activities affecting quality shall be prescribed by documented instructions, procedures, drawings, or operator aids that include quantitative or qualitative acceptance criteria that can be used to determine if activities are satisfactorily accomplished.” The Focus Group discussed the fact that operator aids may not contain “quantitative or qualitative acceptance criteria that can be used to determine if activities are satisfactorily accomplished.” Therefore, the resolution was to change the text into two sentences that read, “Activities affecting quality shall be prescribed by documented instructions, procedures, drawings, or operator aids. When applicable, these documents shall include quantitative or qualitative acceptance criteria that can be used to determine if activities are satisfactorily accomplished.” This change was agreed to by the Focus Group.

The Focus Group agreed to an additional sentence in Section 6.2, “Instructions, Procedures and Drawings.” The sentence adds material found in the QSAS Section 4.1, gray box DOE-1. The approved addition reads, “The organization shall establish a reasonable minimum frequency for reviewing, updating, and re-distributing current revisions of controlled documents and procedures (e.g., SOPs).”

The Focus Group agreed to add a bullet to include “materials management” to the list of administrative activities to be covered by procedures in Section 6.2.1, “Administrative Procedures.” This was suggested as a result of this item being included in the QSAS Section 4.2 gray box DOE-3.

The Focus Group agreed to revise the title of Section 6.3 from “Quality Records” to “Records.”

The Focus Group agreed to add a sentence to Section 6.3, “Records” that says, “The laboratory shall develop and maintain a listing of names, initials, and signatures of individuals who are responsible for signing or initialing any laboratory record.” This was suggested as a result of similar language included in the QSAS Section 4.12 gray box DOE-1.

The Focus Group discussed a newly proposed Section 6.3.3 “Notebooks/Logbooks.” This new section was suggested as a result of similar language included in the QSAS Section 4.12 gray box DOE-6. Some of the issues discussed related to the fact that the terms “notebook” and “logbook” may have specific meanings on the Hanford Site that are unique to some of the companies and the list of requirements provided in the new section may not be universally applicable or achievable. Steve Smith agreed to take the **ACTION ITEM** to review all of Section 6.3 and propose a solution to the issues raised by the group on the issue of logbooks and notebooks. The language, as revised during the meeting, for this section reads:

### **“6.3.3 Notebooks/Logbooks**

The organization shall establish a records management system for control of notebooks/logbooks, including a minimum review frequency. Documentation reviews shall be maintained and available for review.

When notebooks/logbooks are required, loose-leaf binders shall not be used. Notebooks/ logbooks shall have:

- a unique identifier clearly displayed
- sequentially-numbered pages
- entries that are signed and dated by the person responsible for performing the activity at the time the activity is performed
- record entries in chronological order.

When no more entries are to be made on a page, unused portions of the page will be struck out, signed or initialed, and dated. This occurs at the end of the last activity performed or as soon as practical thereafter.”

The Focus Group agreed to add a sentence to provide clarification to Section 10.0, "Assessments" that says, "Surveillances, peer reviews and readiness reviews are acceptable assessment techniques that use observation and monitoring to provide confidence that on-going processes and activities are adequately and effectively performed."

The Focus Group agreed to the proposed revision to split Section 10.2, "Independent Assessments" into two subsections describing requirements associated with internal independent assessments and external assessments. During the meeting, it was stated that this language is consistent with the de minimis change currently found on the HASQARD Focus Group web site. **EDITOR'S NOTE:** Since the May 15 Focus Group meeting, the QA sub-group took another look at Section 10 and the de minimis change on the HASQARD web site. The Sub-Group noticed that the proposed revisions reviewed at the May 15 Focus Group meeting were based on the QA sub-group's "final draft" of proposed revisions and did not completely address the de minimis changes on the web site. The QA sub-group will provide another revision at the next Focus Group meeting.

After discussing Section 10.0 of Volume 1, all proposed revisions resulting from the QSAS/HASQARD gap analysis conducted by the QA sub-group had been reviewed. The Focus Group Secretary proposed that the revisions noted to date will be incorporated in a "changes tracked" version of the Volume 1 to aid in final review of this revision of the document. The Focus Group Chair requested that the Focus Group Secretary distribute the electronic, "changes tracked" version of Volume 1 to the QA sub-group as they resolve the action item noted in these minutes in preparation for next month's meeting. Hearing no objections, the Focus Group Chair adjourned the meeting at 3:59 PM.

The next meeting is scheduled for June 12, 2012 at 2:00 PM in 2420 Stevens, Room 308.